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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,015	HARRISON, PETER	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment filed 05 June 2003 in Paper No. 15 is acknowledged and has been entered. Claims 9 and 10 have been canceled. Claims 1, 2, 5, and 8 have been amended. Claims 11-18 have been added.

2. Claims 1-8 and 11-18 are pending in the application and are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

3. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed December 5, 2002 (Paper No. 12) have been withdrawn.

For clarity of record, the rejections of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Groves, et al (*Hybridoma* **6**: 71-76, 1987) or Groves, et al (*Journal of Endocrinology* **126**: 217-222, 1990) have been withdrawn because the disclosed antibodies do not bind a protein antigen, as required by the present claims. The antibodies disclosed by Grove et al. bind testosterone or progesterone, not to a protein antigen.

The rejection of claims 1-4, 7, and 8 under 35 U.S.C. 102(b) as being anticipated by Yang et al. (*Journal of Molecular Biology* **254**: 392-403, 1995) has been withdrawn for the following reason: The antibodies disclosed by Yang et al. are mutated and/or not naturally occurring.

The rejection of claims 1-5, 7 and 8 under 35 U.S.C. 102(b) as being anticipated by Schier et al. (*Journal of Molecular Biology* **263**: 551-567, 1996) has been withdrawn because Schier et al. teach a very high affinity human single-chain Fv that binds the tumor-associated antigen ErbB2, which was by affinity maturation of a non-naturally occurring antibody.

The rejection of claims 1-8 under 35 U.S.C. 102(b) as being anticipated by Osbourn et al. (*Immunotechnology* **2**: 181-196, 1996) has been withdrawn because the antibody of Osbourn et al. is not a non-mutated, naturally occurring antibody.

The rejection of claim 4 under 35 U.S.C. 102(b) as being anticipated by WO 91/01990 (Shively et al.) has been withdrawn because the non-mutated, naturally occurring antibody disclosed by the prior art is a mouse antibody.

The provision rejection of claims 1-8 are under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 19, and 22-24 of co-pending Application No. 09/786,013 has been withdrawn because co-pending Application No. 09/786,013 has been abandoned.

Claim Objections

4. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 7 depends from claim 1. Claim 7 is drawn to an antibody, which is a single-chain Fv, $F(ab')_2$, Fv, or Fab. Therefore, the antibody of claim 7 is not naturally occurring, as required by claim 1. For this reason claim 7 does not limit the scope of claim 1, but broadens the scope of claim 1 to include non-naturally occurring antibodies.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Groves, et al (*Hybridoma* **6**: 71-76, 1987), as evidenced by Groves et al. (*Hybridoma* **19**: 201-214, 2000).

Groves et al. (1987) teaches an ovine monoclonal antibody that binds testosterone, which has a very high affinity. The antibody of Groves et al. is a natural antibody produced by immunizing a non-rodent mammal a hapten coupled to a protein antigen, namely ovalbumin.

Notably, the claims do not require the antibody to bind specifically to a protein antigen; the claims only require the antibody to be produced by immunizing a non-rodent mammal with a protein antigen.

Groves et al. (2000) teaches sheep antibodies typically have much higher binding affinity constants than the equivalents in mice.

Although Groves et al. (1987) does not characterize the disclosed antibody by the method recited in the claims, Grove et al. (1987) explicitly discloses the antibody is a high affinity antibody having a dissociation constant of 7.63×10^{-12} M. Groves et al. (2000) teaches that sheep antibodies typically have higher binding affinity constants than the equivalents in mice. Therefore, because the antibody of the prior art is a sheep antibody with a very high binding affinity constant, the antibody of the prior art is reasonably deemed the same as the antibody of the instant claims, absent a showing of any differences.

Note: The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed antibody. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed antibody is different than that taught by the prior art.

7. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Groves, et al (*Journal of Endocrinology* **126**: 217-222, 1990), as evidenced by Groves et al. (*Hybridoma* **19**: 201-214, 2000).

Groves et al. (1990) teaches an ovine monoclonal antibody that binds progesterone, which has a very high affinity. The antibody of Groves et al. is a natural

antibody produced by immunizing a non-rodent mammal a hapten coupled to a protein antigen, namely ovalbumin.

Notably, the claims do not require the antibody to bind specifically to a protein antigen; the claims only require the antibody to be produced by immunizing a non-rodent mammal with a protein antigen.

Groves et al. (2000) teaches sheep antibodies typically have much higher binding affinity constants than the equivalents in mice.

Although Groves et al. (1987) does not characterize the disclosed antibody by the method recited in the claims, Grove et al. (1987) explicitly discloses the antibody is a high affinity antibody having a dissociation constant of 4.8 $x10^{-12}$ M. Groves et al. (2000) teaches that sheep antibodies typically have higher binding affinity constants than the equivalents in mice. Therefore, because the antibody of the prior art is a sheep antibody with a very high binding affinity constant, the antibody of the prior art is reasonably deemed the same as the antibody of the instant claims, absent a showing of any differences.

8. Claims 1-6 and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchegger et al. (*Journal of the National Cancer Institute* **79**: 337-342, 1987), as evidenced by Groves et al. (*Hybridoma* **19**: 201-214, 2000).

The term "naturally occurring" is not defined in the specification. Here, the "naturally occurring" monoclonal antibody of claim 1 has been interpreted as an antibody that is produced by immunizing an animal with a protein antigen, so as not to exclude an antibody produced by a hybridoma. This is interpretation is deemed reasonable since a hybridoma is generally produced by fusing a cell that naturally produces an antibody to a myeloma cell; therefore it can be argued that the monoclonal antibody is, or was naturally occurring. Furthermore, claim 11 recites, "a natural antibody [is] produced by immunizing a non-rodent mammal with a protein antigen".

Buchegger et al. teaches a swine monoclonal antibody that binds CEA, which has a very high affinity, i.e., $K_d = 1.2 \times 10^{-10}$ M. Buchegger et al. teaches immunizing a non-rodent mammal with a protein antigen produced the antibody. Bucchegger et al.

discloses that the affinity of this swine antibody is greater than the affinity of the mouse anti-CEA antibody, which was used as the basis for comparisons to determine whether or not the swine antibody has a high affinity.

Groves et al. teaches antibodies produced by larger animals, including pigs, typically have much higher binding affinity constants than the equivalents in mice.

Although Buchegger et al. does not characterize the disclosed antibody by the method recited in the claims, Buchegger et al. explicitly discloses the antibody is a high affinity antibody having a dissociation constant of 1.2×10^{-10} M. Groves et al. teaches that antibodies produced by larger animals, including pigs, typically have much higher binding affinity constants than the equivalents in mice. Therefore, because the antibody of the prior art is a sheep antibody with a very high binding affinity constant, the antibody of the prior art is reasonably deemed the same as the antibody of the instant claims, absent a showing of any differences.

Applicant has traversed the rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Buchegger et al. (*Journal of the National Cancer Institute* **79**: 337-342, 1987) for the reason set forth in the previous Office action. Applicant has argued that the skilled artisan would not immediately recognize that the disclosed antibody falls within the scope of the claims, because the disclosed antibody is not a high affinity antibody. Applicant further argues that there is no reason to believe the antibodies of the prior art possess the acid stability that is critical to the subject invention.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

Buchegger et al. explicitly discloses that that swine antibody has a higher affinity than a comparable mouse antibody. Furthermore, because the antibody has a K_d of 1.2×10^{-10} M, the artisan would recognize that the antibody has a high affinity. Although Buchegger et al. does not disclose that the antibody has been characterized by the method recited in the claims as having acid stability, because the antibody of Buchegger et al. has very high affinity it is expected that the antibody will fulfill the limitations of the claims. Furthermore, it is duly noted that the recited characterization of

the claimed antibody does not alter the chemical and biologic nature of the claimed subject matter, i.e., a high affinity antibody. Therefore, the antibody of the prior art is deemed the same as the antibody of the claims, absent a showing of any difference. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed antibody. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed antibody is different than that taught by the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA, 1977) and *Ex parte Gray*, 10 USPQ2d 1922 1923 (PTO Board of Patent Appeals and Interferences, 1988 and 1989).

9. Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/01990 (Shively et al.).

The term "naturally occurring" is not defined in the specification. Here, the "naturally occurring" monoclonal antibody of claim 1 has been interpreted as an antibody that is produced by immunizing an animal with a protein antigen, so as not to exclude an antibody produced by a hybridoma. This is interpretation is deemed reasonable since a hybridoma is generally produced by fusing a cell that naturally produces an antibody to a myeloma cell; therefore it can be argued that the monoclonal antibody is, or was naturally occurring. Furthermore, claim 11 recites, "a natural antibody [is] produced by immunizing a non-rodent mammal with a protein antigen".

Shively et al. teaches a mouse antibody produced by hybridoma T84.66, which binds CEA and has a very high affinity.

Although Shively et al. does not characterize the disclosed antibody by the method recited in the claims, Shively et al. explicitly discloses the antibody is a high affinity antibody with a binding affinity constant of 2.6×10^{-10} M. Therefore, the antibody of Shively et al. is deemed the same as the antibody of the instant claims, absent a showing of any differences.

Applicant has traversed the rejection of claims 1-3, 5, and 6 under 35 U.S.C. 102(b) as being anticipated by Shively et al. for the reason set forth in the previous Office action. Applicant has argued that the skilled artisan would not immediately recognize that the disclosed antibody falls within the scope of the claims, because the disclosed antibody is not a high affinity antibody. Applicant further argues that there is no reason to believe the antibodies of the prior art possess the acid stability that is critical to the subject invention.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

Shively et al. explicitly discloses that that mouse antibody has a K_d of 2.6×10^{-10} M, so the artisan would recognize the antibody as having a high affinity. Although Shively et al. does not disclose that the antibody has been characterized by the method recited in the claims as having acid stability, because the antibody of Shively et al. has very high affinity it is expected that the antibody will fulfill the limitations of the claims. Furthermore, it is duly noted that the recited characterization of the claimed antibody does not alter the chemical and biologic nature of the claimed subject matter, i.e., a high affinity antibody. Therefore, the antibody of the prior art is deemed the same as the antibody of the claims, absent a showing of any difference. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed antibody. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed antibody is different than that taught by the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA, 1977) and *Ex parte Gray*, 10 USPQ2d 1922 1923 (PTO Board of Patent Appeals and Interferences, 1988 and 1989).

10. Claims 1-5 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Flynn et al. (*Journal of Immunological Methods* **121**: 237-246, 1989), as evidenced by Jacobsen et al. (*Am. J. Surg. Pathol.* **5**: 257-266, 1981) and Groves et al. (*Hybridoma* **19**: 201-214, 2000).

The term "naturally occurring" is not defined in the specification. Here, the "naturally occurring" monoclonal antibody of claim 1 has been interpreted as an antibody that is produced by immunizing an animal with a protein antigen, so as not to exclude an antibody produced by a hybridoma. This is interpretation is deemed reasonable since a hybridoma is generally produced by fusing a cell that naturally produces an antibody to a myeloma cell; therefore it can be argued that the monoclonal antibody is, or was naturally occurring. Furthermore, claim 11 recites, "a natural antibody [is] produced by immunizing a non-rodent mammal with a protein antigen".

Jacobsen et al. teaches human chorionic gonadotropin is a tumor-associated antigen. Groves et al. teaches sheep antibodies typically have much higher binding affinity constants than the equivalents in mice.

Flynn et al. teaches a non-mutated, naturally occurring sheep monoclonal antibody, which binds human chorionic gonadotropin. Flynn et al. teach immunizing sheep with a protein antigen produced the antibody.

Although Flynn et al. does not teach the disclosed antibody has a high affinity and does not disclose that the antibody can be characterized by the method recited in the claims, because the antibody is a sheep antibody, the antibody is presumed to have a high affinity, because Groves et al. teaches that sheep antibodies typically have higher binding affinity constants than the equivalents in mice. Therefore, the antibody of Flynn et al. is deemed the same as the antibody of the instant claims, absent a showing of any differences.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-8 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchegger et al. (*Journal of the National Cancer Institute* **79**: 337-342, 1987), as evidenced by Groves et al. (*Hybridoma* **19**: 201-214, 2000), in view of Adams et al. (*Cancer Research* **58**: 485-490, 1998).

Claims 1-7 are drawn to a non-mutated, naturally occurring high affinity antibody, which has binding affinity to a protein antigen and which can be characterized by the specifically recited process set forth in the claims. Claims 11-17 are drawn to a high affinity antibody, or a recombinantly produced version thereof, which antibody is a natural antibody produced by immunizing a non-rodent mammal with a protein antigen and which antibody can be characterized by the specifically recited process set forth in the claims. Claims 4 and 14 require the antibody to be a non-rodent antibody. Claims 5 and 15 require the antibody to have affinity for a tumor-associated antigen. Claims 6 and 16 require the antigen of claims 5 and 15 to be carcinoembryonic antigen (CEA). Claims 7 and 17 require the antibody of claims 1 and 11 to be a single-chain antibody derived an antibody according to claims 1 and 11 or an antigen-binding fragment of thereof. Claims 8 and 18 are drawn to a variant of the antibody according to claims 7 and 17, respectively, wherein the specifically recited process can be used to characterize said variant.

The term "naturally occurring" is not defined in the specification. Here, the "naturally occurring" monoclonal antibody of claim 1 has been interpreted as an antibody that is produced by immunizing an animal with a protein antigen, so as not to exclude an antibody produced by a hybridoma. This is interpretation is deemed reasonable since a hybridoma is generally produced by fusing a cell that naturally produces an antibody to a myeloma cell; therefore it can be argued that the monoclonal antibody is, or was naturally occurring. Furthermore, claim 11 recites, "a natural antibody [is] produced by immunizing a non-rodent mammal with a protein antigen".

Groves et al. (2000) teaches that antibodies produced by larger animals, including pigs, typically have much higher binding affinity constants than the equivalents in mice.

Buchegger et al. teaches that which is set forth above. In addition, Buchegger et al. teaches repeated administration of mouse monoclonal antibodies may induce the production of anti-rodent immunoglobulin. Buchegger et al. teaches swine antibodies have a low common antigenicity with mouse immunoglobulin and may be less immunogenic in humans than mouse antibodies. Accordingly, Buchegger et al. teaches that swine antibodies against CEA can be used advantageously to detect tumors in patients by immunoscintigraphy or to treat patients having tumors by radioimmunotherapy. Buchegger et al. discloses that the swine monoclonal antibody, which has the higher affinity and which binds with high specificity to CEA, is a particularly suitable for clinical use.

Although Buchegger et al. does not characterize the disclosed antibody by the method recited in the claims, Buchegger et al. explicitly discloses the antibody is a high affinity antibody having a dissociation constant of 1.2×10^{-10} M. Again, Groves et al. (2000) teaches that antibodies produced by larger animals, including pigs, typically have much higher binding affinity constants than the equivalents in mice. Therefore, because the antibody of the prior art is a pig antibody with a very high binding affinity constant, the antibody of the prior art is reasonably deemed the same as the antibody of the instant claims, absent a showing of any differences.

Buchegger et al. does not explicitly teach the antibody can be single-chain antibody or antigen-binding fragment of an antibody, as required by the limitation of claims 7 and 17. Furthermore, Buchegger et al. does not teach or suggest a variant of a single-chain antibody derived from the antibody of claims 1 or 11, as set forth in claims 8 and 18.

Adams et al. teaches compared to IgG molecules, antigen-binding fragments thereof, e.g., Fab, and single-chain antibodies (scFv) derived therefrom exhibit "significantly improved tumor specificity and intratumoral penetration" [citations omitted] (page 485, column 2). Accordingly, Adams et al. suggests that single-chain antibodies and antigen-binding fragments of antibodies can be used advantageously to detect tumors in patients or to treat patients having tumors. In addition, Adams et al. teaches that it has proven possible to significantly increase antibody fragment or single-chain

antibody affinity by the process of affinity maturation. Adams et al. teaches that this process can be used to produce a variant of a single-chain antibody, which has increased affinity to the antigen compared to the parental antibody. Adams et al. teaches increased affinity leads to improved selective tumor delivery of single-chain antibodies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to produce a single-chain antibody or antigen-binding fragment, i.e., Fab, or a variant thereof, from the antibody of Bucheggar et al. for use in detecting tumors in patients or for use in treating patients having tumors, because Adams et al. suggests single-chain antibodies and antigen-binding fragments of antibodies can be used advantageously to detect tumors in patients or to treat patients having tumors and because Adams et al. teaches variants of single-chain antibodies can be produced, which have even greater binding affinity. One of ordinary skill in the art at the time the invention was made would have been motivated to produce a single-chain antibody or antigen-binding fragment, i.e., Fab, from the antibody of Bucheggar et al., because Adams et al. teaches such single-chain antibodies or antigen-binding fragments of antibodies significantly improve tumor specificity and intratumoral penetration.

Conclusion

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Flynn et al. (1990) teaches ovine monoclonal antibodies that bind synthetic peptides of foot-and-mouth disease virus.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
December 29, 2003